

Patient Information Sheet: Clozapine (marketed as Clozaril)

This is a summary of the most important information about Clozaril (from the FDA's web site).

What is Clozaril?

Clozaril is a medicine used to treat people with severe forms of schizophrenia that have not responded to or can't take other treatments and is used to lower risk of suicidal behavior in those with schizophrenia or schizoaffective disorder.

Who Should Not Take Clozaril? You should not take Clozaril if:

- ◆ You take other medicines that can cause the same serious bone marrow side effects as Clozaril.

What are The Risks?

The following are the risks and potential side effects of Clozaril therapy. However, this list is not complete.

Increased chance of death in elderly persons. Elderly patients treated with atypical antipsychotics, such as Clozaril, for dementia had a higher chance for death than patients who did not take the medicine. Clozaril is not approved for dementia.

Agranulocytosis, a potentially life-threatening reaction where the body's bone marrow does not produce enough white blood cells. Because of this risk, your healthcare professional must monitor your blood while you are taking Clozaril.

Seizures. The risk of seizure is increased in people who have a history of seizures or other predisposing factors. Because of this risk you should not engage in any activity where you may suddenly lose consciousness, such as operating complex machinery, driving, swimming, climbing, etc.

Heart problems. Clozaril can cause a condition called myocarditis, or swelling of the heart muscle. Some of the warning signs of myocarditis are tiredness, shortness of breath, rapid breathing, fever, chest pain, and irregular heart beat.

Lowering of blood pressure when you stand up. This may also lead to fainting. In rare instances, this has been associated with lung and/or heart collapse.

Clozaril and other antipsychotic medications can cause serious problems such as:

A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS). NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. It can affect your kidneys and is a medical emergency.

A movement problem called tardive dyskinesia (TD). Characterized by muscle movements that cannot be stopped.

High blood sugar and diabetes. Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.

Other serious side effects may include fever, blood clots in the lung, increased blood sugar, and liver disease.

The most common side effects include drowsiness, increased salivation, rapid heart beat, dizziness, constipation, headache, shaking, and lightheadedness.

What Should I Tell My Healthcare Professional?

Before you start taking Clozaril, tell your healthcare professional if you:

- ◆ have or had glaucoma
- ◆ have or had heart or lung problems
- ◆ have or had seizures
- ◆ have or had stomach problems
- ◆ have or had blood clots
- ◆ have or had prostate enlargement
- ◆ drink alcohol
- ◆ have or had diabetes or increased blood sugar
- ◆ smoke
- ◆ are trying to become pregnant, are already pregnant, or are breast-feeding.
- ◆ have or had liver disease

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with Clozaril, review all medications with your health care professional, including those that you take without a prescription. You should not take Clozaril if you are taking other medicines that can cause the same serious bone marrow side effects as Clozaril. Your healthcare professional may have to adjust your dose or watch you more closely if you take the following medications:

- ◆ epinephrine
- ◆ cimetidine (Tagamet)
- ◆ fluvoxamine (Luvox)
- ◆ phenytoin (Dilantin)
- ◆ erythromycin
- ◆ paroxetine (Paxil)
- ◆ rifampin
- ◆ carbamazepine
- ◆ Avoid drinking alcohol
- ◆ certain drugs used to treat anxiety, called benzodiazepines
- ◆ certain drugs used to clear thoughts, called psychotropics

Is There Anything Else I Need to Know?

Dizziness, and sometimes fainting, caused by a drop in blood pressure may happen with Clozaril, especially when you first start taking this medicine or when the dose is increased.

Clozaril may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how Clozaril affects you.